Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

Protocol summary

Study aim
Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

Design
This study is a clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients.

Settings and conduct
This study is performed in patients referred to Imam Reza Hospital and Imam Khomeini Hospital in Kermanshah. Blinding is done for all patients and clinical caregivers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with diabetic ulcer Exclusion criteria: Pregnant women - Children - People undergoing chemotherapy - People receiving corticosteroids. - Patients suffering from liver and kidney failure.

Intervention groups
In the intervention group, wound treatment with ointment, herbal detergent and routine dressing In the control group, perform routine puncture and wound routine

Main outcome variables
Wound severity Wound area Wound site Wound depth Exodus Type of texture Pain score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201213049703N1**
Registration date: **2021-02-10, 1399/11/22**
Registration timing: **prospective**
Last update: **2021-02-10, 1399/11/22**
Update count: **0**

Registration date
2021-02-10, 1399/11/22

Registrant information

Name
Toraj Ahmadi Jouybari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3727 2049

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

Public title
Effect of herbal ointment in treatment of ulcers diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic ulcers

Exclusion criteria:

Pregnant women Patients suffering from liver and kidney failure Childern People undergoing chemotherapy People receiving corticosteroids.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization and assigning people to groups The random number function is used using Excel software as follows: First, in a column, the groups are entered as A, B and below. In the opposite column, random numbers are generated using the RAND command. In the next step, using the sort command, random numbers are generated from small to large or vice versa, which causes the order of the groups, A, B, to be changed. Using the new order, people are assigned to different groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Herbal ointments and routine treatment ointments are designed to be the same in terms of color and odor so that they are not recognizable to the patient and the caregiver. And only the statistical analyst should be aware of the ointment used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah, Shahid Beheshti Blvd., Kermanshah University of Medical Sciences

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Province

Kermanshah

Postal code

6715847141

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.KUMS.REC.1399.073

Health conditions studied

1

Description of health condition studied

Ulcers diabetes

ICD-10 code

E11.4

ICD-10 code description

Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description

PUSH Score

Timepoint

Every week until the 12th week

Method of measurement

Based on the characteristics of diabetic ulcers

Secondary outcomes

1

Description

Wound area

Timepoint

Every week until the 12th week

Method of measurement

With a caliper, the dimensions of the wound, including the length and width of the wound, are measured and its area is calculated

2

Description

Wound depth

Timepoint

Every week until the 12th week

Method of measurement

Wound depth is measured with forceps and calipers

Intervention groups

1

Description

The herbal ointment of the design containing thirsty

plant extract, honey, black seed oil, mazo will be provided to the patients of the intervention group in the form of ready-to-use tubes without printing of the design. Contains thirst extract, apple cider vinegar and normal saline, washed and dried with sterile gauze. The herbal ointment is then applied to the wound with a watering can and fixed with a four-layer sterile dry gauze with anti-allergy adhesive. Changing the dressing and using the ointment should be done once a day for the necessary time. (Depending on the patient's condition until complete treatment)

Category

Treatment - Other

2

Description

Liam topical ointment (manufacturer of Mehr Miracle Researchers) containing chamomile extract, 8% cow's eye, 13% beeswax and 17% honey as a routine ointment of Imam Khomeini Hospital in Kermanshah in the form of ready-to-use tubes without printing. Patients in intervention group 2 will be included. The procedure will be performed by washing the wound and surrounding tissues with normal saline solution and drying them with sterile gauze. Liam ointment is then applied to the wound with a watering can and fixed with a four-layer sterile dry gauze with anti-allergy adhesive. Changing the dressing and using the ointment should be done once a day for the necessary time. (Depending on the patient's condition until complete treatment)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital

Full name of responsible person

Toraj Ahmadi Jouybari

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Kermanshah -Naghlieh Ave- Imam Khomeini Hospital

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Toraj Ahmadi Jouybari

Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Results can be shared after not identifying people.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
All interested people
Under which criteria data/document could be used
For the use of other researchers
From where data/document is obtainable
Toraj Ahmadi Jouybari dr.ahmadi_jouybari@yahoo.com
What processes are involved for a request to access data/document
1. Send request to email 2. The purpose of the data request should be clear. 3. If approved by the main executor, action will be taken immediately
Comments